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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,553	04/08/2004	Wilfried Fischer	29473/11372A	8366

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EXAMINER	
GILBERT, ANDREW M	
ART UNIT	PAPER NUMBER
3767	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/820,553	FISCHER ET AL.	
	Examiner	Art Unit	
	Andrew M. Gilbert	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,6,7,11-14 and 16-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,6,7,11-14 and 16-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/16/2007 has been entered.

Acknowledgements

2. This office action is in response to the reply filed on 1/16/2007.

3. In the reply, the Applicant amended claims 1 and 16.

4. Additionally, the applicant submitted replacement drawings to obviate the objection to the drawings and correctly provided clarification to obviate the objection to the claims by noting that the "-," on ln 3 really was a strickout of the comma indicating that the comma has been deleted from the claim.

5. Finally, the Applicant filed a terminal disclaimer to obviate the double patenting rejection; however, the terminal disclaimer has been disapproved, as the attorney is not of record. Thus, the double patenting rejection stands. The attorney, Michael Mucyznski (48,642) is not listed as an attorney of the record in the Oath and Declaration and there is no valid customer number provided in the Oath and Declaration or in any correspondence. The Examiner recommends two courses of action: 1) resubmit the Terminal Disclaimer and check box #1 on the terminal disclaimer form which indicates

that "For submissions on behalf of a business/organization ... the undersigned is empowered to act on behalf of the business/organization"; or 2) resubmit the Terminal Disclaimer and file a new form indicating the customer number (04743) for the case or filed a power of attorney indicating that Michael Mucyznski is an attorney of record for the case.

6. Claims 1, 2, 4, 6, 7, 11-14, 16-27 are pending for examination.

Claim Objections

7. Claim 16 is objected to because of the following informalities: Claim 1 recites the limitation "comprise" on ln 3. The Examiner believes the limitation should read "comprising". Appropriate correction is required.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1, 2, 4, 6, 7, 11-13, 16-20, 22-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Avarhami (6148232) in view of Hofmann et al (6192270).

10. In reference to independent claim 1, Avarhami discloses a transdermal delivery system comprising: a carrier layer (70) impermeable to a substance to be delivered and comprising one or more electrodes (Fig 1b; 58; col 12, lns39-42); a reservoir (74) containing said substance to be delivered, the reservoir being formed by a contact adhesive (74; col 12, lns 46-57; wherein the Examiner notes that the Examiner has

considered a contact adhesives to be any substance that adheres on contact and the disclosed reservoir of Avarhami is fully capable of being a contact adhesive as the reservoir (74) adheres to both sides of the electrode patch (70) in Fig 1b) and provided stacked between the carrier layer and one or more counter electrodes (70, 74, 120, Fig 1b); a battery (52); an integrated controller microchip that is fixed to the carrier layer and programmable to a prescription (30, 50, col 11, lns 62-col 12, lns 2; also see Fig 3, col 13, lns 19-col 14, lns 8); a reading and writing device (Fig 3; col 11, lns 62-col 12, lns 2; also see Fig 3, col 13, lns 19-col 14, lns 8).

11. In reference to independent claim 16, Avarhami discloses a transdermal delivery system comprising: a carrier layer (part of 70 on top of 74; Fig 1b) impermeable to a substance to be delivered; a membrane (part of 70 below of 74; Fig 1b) permeable to said substance to be delivered; a reservoir (74) containing said substance to be delivered, the reservoir being provided stacked between the carrier layer and the membrane (74, Fig 1b); a battery (50); an integrated controller microchip (30, 50, col 11, lns 62-col 12, lns 2; also see Fig 3, col 13, lns 19-col 14, lns 8) fixed to the carrier layer; and a reading and writing device (Fig 3; col 11, lns 62-col 12, lns 2; also see Fig 3, col 13, lns 19-col 14, lns 8), wherein the carrier layer and the membrane comprise one or more electrodes such that the one or more electrodes of the membrane serve(s) as counterelectrode(s) to the one or more electrodes of the carrier layer (Fig 1b; col 12, lns 50-57).

12. In reference to claim 2 (see (Fig 2; col 12, lns 66-col 13, lns 19)); claim 4, 17 (see (col 14, lns 1-35)); claim 6, 19 (see (col 14, lns 62-63)); claim 7, 20 (see (Figs 2-3; col

13, lns 1-col 14, ln 8)); claim 11, 24 (see (Fig 1b)); claim 12, 25 (see (col 11, lns 62-col 12, lns 2)); claim 13, 26 (see (52)); claim 18 (see (74; col 12, lns 46-57)); claim 22 (see (Fig 2; 75, 60; col 13, lns 1-35)); claim 23 (see (Fig 1b, 58, 120)).

13. However, Avarhami does not expressly disclosing a layer consisting of a pressure-sensitive contact adhesive applied to the side of the membrane remote from the reservoir or a removable film. Hoffman et al teaches that it is known to have a layer (col 3, lns 31-54) consisting of a pressure-sensitive contact adhesive applied to the side of the membrane remote from the reservoirand a removable film (col 3, lns 51-54) for the purpose of providing a protective cover that can be peeled off before use and adhesive to adhere to the skin of a patient (col 3, lns 51-54). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by Avarhami with the adhesive and removable film as taught by Hofmann et al for the purpose of providing a protective cover that can be peeled off before use and adhesive to adhere the device to the patient during use (col 3, lns 51-54).

14. Claim 1, 4, 12-13, 16-18, 21, 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Corish et al (5533995) in view of Hofmann et al (6192270).

15. In reference to independent claim 1, Corish et al discloses a transdermal delivery system comprising: a carrier layer (23) impermeable to a substance to be delivered and comprising one or more electrodes (14); a reservoir (12) containing said substance to be delivered, the reservoir being formed by a contact adhesive (col 3, lns 52-col 4, lns

35) and provided stacked between the carrier layer and one or more counter electrodes (23, 12, 12, 13; Fig 1); a battery (17; col 5, lns 57-62); an integrated controller microchip (18; col 6, lns 9-13, 54-64; col 8, lns 66-67) that is fixed to the carrier layer and programmable to a prescription; a reading and writing device (18; col 6, lns 9-13, 54-64; col 8, lns 66-67).

16. In reference to independent claim 16, Corish et al discloses a transdermal delivery system comprising: a carrier layer (23) impermeable to a substance to be delivered; a membrane (13) permeable to said substance to be delivered; a reservoir (12) containing said substance to be delivered, the reservoir being provided stacked between the carrier layer and the membrane (Fig 1); a layer (col 7, lns 3-6) consisting of a pressure-sensitive contact adhesive applied to the side of the membrane remote from the reservoir; a battery (17); an integrated controller microchip (18; col 6, lns 9-13, 54-64; col 8, lns 66-67) fixed to the carrier layer; and a reading and writing device (18; col 6, lns 9-13, 54-64; col 8, lns 66-67), wherein the carrier layer and the membrane comprise one or more electrodes such that the one or more electrodes of the membrane serve(s) as counterelectrode(s) to the one or more electrodes of the carrier layer (col 8, lns 29-39).

17. In reference to claim 4, 17 (see (col 3, lns 22-29)); claim 12, 25 (see (18; col 6, lns 9-13, 54-64; col 8, lns 66-67)); claim 13, 26 (see (col 5, lns 58-62)); claim 18 (see (col 3, lns 52-col 4, lns 35)); claim 21 (see (col 8, lns 12-18)).

18. However, Corish et al does not expressly disclosing a removable film. Hoffman et al teaches that it is known to have a removable film (col 3, lns 51-54) for the purpose of

providing a protective cover that can be peeled off before use (col 3, lns 51-54). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by Corish et al with the removable film as taught by Hofmann et al for the purpose of providing a protective cover that can be peeled off before use (col 3, lns 51-54).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

19. Claims 1, 2, 4, 6, 7, 11-14, 16-27 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6757560. Although the conflicting claims are not identical, they are not patentably distinct from each other because the pending application is merely more

broad to the patented parent application and it has been held that the broader invention is anticipated by the narrow patented parent application.

Response to Arguments

20. Applicant's arguments with respect to claims 1, 2, 4, 6, 7, 11-14, 16-27 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Reller et al (5002527); Korenstein et al (5964726); Hofmann et al (6748265); Muroki (5944685); Palti (2001/0023330); and Zhang et al (6340472).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Andrew Gilbert

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER